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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/521,634 | 10/11/2005 | Brian Seed | 00786/432002 | 4930 |

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| EXAMINER |
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WILSON, MICHAEL C

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| ART UNIT | PAPER NUMBER |
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1632

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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| 31 DAYS | 01/19/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/521,634

Applicant(s)

SEED ET AL.

Examiner

Michael C. Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 30-39 have been canceled. Claims 1-29 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, 18 and 19, drawn to a method of making a cell with one genetic mutation using an artificial chromosome, classified in class 435, subclass 455.
- II. Claims 1-19, drawn to a method of making a cell with two or more genetic mutations by introducing more than one artificial chromosome, classified in class 435, subclass 455.
- III. Claims 1, 20-23 and 26-29, drawn to a method of making a genetically modified non-human mammal having one genetic mutation using cells comprising an artificial chromosome having one genetic mutation, classified in class 800, subclass 21.
- IV. Claims 1, 20-29, drawn to a method of making a genetically modified non-human mammal having at least two genetic mutations, classified in class 800, subclass 21 and 22.

The inventions are distinct, each from the other because of the following reasons:

Claims 1-12, 18 and 19 are generic to Groups I and II.

The products made in the methods of Groups I and II are related as combination and subcombination. Products made by methods in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the

subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (making genetically modified cells comprising at least two mutations) in the method of Group II as claimed does not require the particulars of the subcombination as claimed because making genetically modified cells having two genetic mutations using an artificial chromosome can be made with an artificial chromosome having two mutations; steps a) and b) of claim 1 do not have to be repeated as in claim 13. The subcombination (making genetically modified cells having one mutation) has separate utility such as making cells having a disruption in one gene and a particular phenotype vs. making cells having a disruption in two genes having a different phenotype. Since the genetically modified cells comprising one mutation and two mutations are patentably distinct, the method of making genetically modified cells having one mutation and the method of making genetically modified cells having two or more mutations are patentably distinct.

The examiner has required restriction between methods of making combination and subcombination products. Where applicant elects the method of making the subcombination (making genetically modified cells having one mutation), and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present

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application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Claim 1 is generic to Groups I and III.

The products made in the methods of Groups I and III are related as combination and subcombination. Products made by methods in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (making a genetically modified non-human mammal) as claimed does not require the particulars of the subcombination as claimed because making a genetically modified non-human mammal can be made by injecting the artificial chromosome directly into an embryo; i.e. cells comprising the artificial chromosome do not have to be inserted into a non-human embryo as claimed. The subcombination (making genetically modified cells comprising an artificial chromosome) has separate utility such as being used for making genetically modified cells used in in vitro assays.

The examiner has required restriction between combination and subcombination. Where applicant elects the subcombination (making genetically modified cells), and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present

application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Claim 1 is generic to Groups I and IV. Claim 25 appears to be limited to making a non-human mammal having at least two mutations and is, therefore, limited to Group IV.

The products made in the methods of Groups I and IV are related as combination and subcombination. Products made by methods in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (making a genetically modified non-human mammal having at least two mutations) as claimed does not require the particulars of the subcombination as claimed because making a genetically modified non-human mammal having at least two mutations can be made with cells having an artificial chromosome having two mutations or by injecting an artificial chromosome having two mutations directly into an embryo; i.e. cells comprising an artificial chromosome do not have to be inserted into a non-human embryo as claimed and two offspring do not have to be used to make the genetically modified non-human mammal. The subcombination (making genetically modified cells comprising an artificial chromosome) has separate utility such as being used for making genetically modified cells used in in vitro assays.

The examiner has required restriction between combination and subcombination. Where applicant elects the subcombination (making genetically modified cells), and

claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Claim 1 is generic to Groups II and III.

The products made in the methods of Groups II and III are related as combination and subcombination. Products made by methods in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (making a genetically modified non-human mammal) as claimed does not require the particulars of the subcombination as claimed because making a genetically modified non-human mammal can be made by injecting the artificial chromosome directly into an embryo; i.e. cells comprising the artificial chromosome do not have to be inserted into a non-human embryo as claimed (claim 20). The subcombination (making genetically modified cells comprising an artificial chromosome) has separate utility such as being used for making genetically modified cells used in in vitro assays.

The examiner has required restriction between combination and subcombination. Where applicant elects the subcombination (making genetically modified cells), and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Claim 1 is generic to Groups II and IV.

The products made in the methods of Groups II and IV are related as combination and subcombination. Products made by methods in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (making a genetically modified non-human mammal having at least two mutations) as claimed does not require the particulars of the subcombination as claimed because making a genetically modified non-human mammal having at least two mutations can be made by injecting an artificial chromosome having two mutations directly into an embryo; i.e. two offspring do not have to be used to make the genetically modified non-human mammal as in claim 24. The subcombination

(making genetically modified cells comprising an artificial chromosome) has separate utility such as being used for making genetically modified cells used in in vitro assays.

The examiner has required restriction between combination and subcombination. Where applicant elects the subcombination (making genetically modified cells), and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Claims 1, 20-23 and 26-29 are generic to Groups III and IV.

The methods of Groups III and IV are related as combination and subcombination. Products made by methods in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (making a genetically modified non-human mammal having at least two mutations) as claimed does not require the particulars of the subcombination as claimed because making a genetically modified non-human mammal having at least two mutations can be made by injecting an artificial chromosome having two mutations directly into an embryo; i.e. making a non-human mammal with two genetic mutations

does not require mating two offspring as in claim 24. The subcombination, making genetically modified non-human mammals, has separate utility such as being used for making different models of disease; non-human mammals with one mutation have a different phenotype than those with two mutations.

The examiner has required restriction between combination and subcombination. Where applicant elects the subcombination (making genetically modified non-human mammals having at least two mutations), and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The burden required to search any two groups together would be undue.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson



**MICHAEL WILSON
PRIMARY EXAMINER**